UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

AMY ARNOLD *Plaintiff*	)	
v.	)	Case No. 2:22-cv-01951-EAS-EPD
	)	District Judge Edmund A. Sargus, Jr. Magistrate Judge Elizabeth Preston Deavers
COOPERSURGICAL, INC., THE COOPER COMPANIES, INC., FEMCARE, LTD. – UK SUBSIDIARY OF UTAH MEDICAL PRODUCTS, INC., and UTAH MEDICAL PRODUCTS, INC. *Defendants*	)	

PLAINTIFF'S FIRST AMENDED COMPLAINT AND JURY DEMAND

NOW COMES Plaintiff, Amy Arnold (hereinafter "Plaintiff" and/or "Ms. Arnold") by and through her counsel, Griffin Purnell LLC and The Henry Law Firm and for her cause of action against Defendants CooperSurgical, Inc., The Cooper Companies, Inc., Femcare, Ltd. – UK subsidiary of Utah Medical Products, Inc., and Utah Medical Products, Inc. (collectively hereinafter "Defendants"), all jointly and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold the Filshie Clip medical device that was surgically used in Plaintiff and others throughout the United States and the world. Accordingly, Plaintiff alleges and states to the Court as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to recover damages within the jurisdictional limits of this Court including all (1) General Damages; (2) Special Damages; and (3) Punitive Damages as well as all other damages allowable under Ohio law as a result of the use, design, manufacture,

EXHIBIT A

surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of Filshie Clips.

2. Plaintiff brings claims fully set forth below asserting: (1) Strict Products Liability for Design Defect under the Ohio Product Liability Act; (2) Strict Products Liability for Manufacturing Defect under the Ohio Product Liability Act and ; (3) Strict Products Liability for Failure to Warn under the Ohio Product Liability Act.

3. This claim arises from Ms. Arnold's Filshie Clip tubal ligation procedure which, because of Defendants' actions and omissions, resulted in a series of damages.

II. PARTIES

4. Plaintiff, Amy Arnold lives in Columbus, Ohio, and is subject to the jurisdiction of this Court, and is deemed to be a resident of the State of Ohio for purposes of venue and jurisdiction.

5. Defendant, The Cooper Companies, Inc. ("Cooper Companies") is a Delaware corporation with its principal place of business located at 6101 Bollinger Canyon Road, in San Ramon, California. For diversity of citizenship purposes, Defendant Cooper Companies, Inc. is a citizen of both Delaware and California. Cooper Companies, Inc. may be served with process by serving its registered agent at 251 Little Falls Drive, Wilmington, DE 19808.

6. Defendant CooperSurgical, Inc. ("CooperSurgical") is a Delaware corporation with its principal place of business located at 95 Corporate Drive in Trumbull, Connecticut. CooperSurgical may be served with process by serving its registered agent at CooperSurgical, Inc., 95 Corporate Drive, Trumbull, CT 06611.

7. Defendant Femcare, Ltd. is a UK subsidiary of Utah Medical Products, Inc. with its principal place of business located at 32 Premier Way, Romsey, Hampshire SO51 9DQ, United

Kingdom. Femcare, Ltd. – UK Subsidiary of Utah Medical Products, Inc. may be served with process by serving its registered agent Karen Elizabeth Glasbey, FemcareUK, 32 Premier Way, Romsey, Hampshire, United Kingdom SO519DQ.

8. Defendant Utah Medical Products, Inc. is the parent company of Femcare, Ltd. with its principal place of business located at 7043 South 300 West, Midvale, Utah 84047-1048 and may be served with process by serving its registered agent Ben Shirley at 7043 South 300 West, Midvale, UT 84047.

9. CooperSurgical is a subsidiary of Defendant Cooper Companies, Inc. Defendant CooperSurgical is a citizen of both Delaware and Connecticut for diversity of citizenship purposes. Cooper Companies, Inc. and CooperSurgical, Inc. are referred to collectively hereinafter as "CooperSurgical."

10. Femcare, Ltd. is a UK subsidiary of Utah Medical Products, Inc., and a citizen of England for diversity of citizenship purposes. Utah Medical Products, Inc. is a citizen of Utah for diversity of citizenship purposes.

11. All acts and omissions of the Defendants as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of its respective agencies, services, employments and/or ownership.

III. JURISDICTION & VENUE

12. This Court has subject matter original jurisdiction through diversity of citizenship pursuant to 28 U.S.C. §1332(a) because the Plaintiff is a citizen of Ohio, the named Defendants are citizens of different states and the amount in controversy exceeds the sum of value of $75,000.00, exclusive of interest and costs.

13. This Court has specific jurisdiction over these Defendants because they

purposefully availed themselves of the privilege of conducting business in the state of Ohio and established minimum contacts sufficient to confer jurisdiction over these Defendants, and the assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with constitutional requirements of due process.

14. CooperSurgical, Femcare, Ltd., and Utah Medical Products sell their products and intend that they be used by medical professionals treating patients in Ohio.

15. At all times relevant hereto and alleged herein, the Defendants conducted and continue to regularly conduct substantial business within the state of Ohio which included and continues to include, the research, safety surveillance, manufacture, sale, distribution and/or marketing of Filshie Clips which are distributed through the stream of interstate and intrastate commerce in the state of Ohio, and within the Southern District of Ohio.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacts business affairs and conducts activity that gave rise to the claim of relief in this District.

IV. FACTUAL BACKGROUND

a. *Plaintiff Brings this Action Because Filshie Clips Injured her after migration.*

17. Plaintiff in this action seeks compensation for injuries she sustained in connection from the use of Filshie Clips, a medical device used in tubal ligations.

18. This action is brought by Plaintiff. Ms. Arnold was implanted with a female birth control device known as a Filshie Clip. In short, this device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by applying a clip onto the fallopian tubes which then anchors

and elicits tissue growth, theoretically causing a closure of the tubes. However, in reality, the clips migrate from the tubes wreaking havoc on the female body.

b. What is a Filshie Clip and How is it Supposed to Work?

19. Filshie Clips are part of the "Filshie Clip system" for laparoscopic tubal ligation which involves applying a titanium clip with silicone rubber lining around each of the fallopian tubes.

20. The Filshie Clip works by exerting continued pressure on the fallopian tube, causing avascularization for the 3 to 5 mm area it encompasses. The silicone continues this pressure even after necrosis starts and the fallopian tube decreases in size. Fibrosis then occurs, and the clip is peritonealized if all goes as planned.

21. Defendants' disposable delivery system consists of an applicator which allows insertion into the women's body to allow the clip to be snaped onto the fallopian tube.

22. A women's choice of birth control is a deeply personal decision, particularly when choosing a long-acting form of birth control like a tubal ligation which should permanently alter a women's body.

c. Background on Filshie Clips and the FDA Process.

23. Femcare, the manufacturer of the Filshie Clip, obtained Conditional Premarket Approval (PMA) by the Food and Drug Administration (FDA). The Defendants' failure to conform with the FDA requirements prescribed in the PMA and violations of relevant state and federal law form the basis of this lawsuit.

24. Class III medical devices are those that either "present a potential unreasonable risk of illness or injury or are for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360(c)(1)(c)

25. Because Filshie Clips are classified as a Class III medical device the FDA evaluated Filshie Clips' safety and effectiveness prior to granting the product Conditional PMA in 1996.

26. At that time, the FDA authorized its commercial distribution. Such approval was contingent upon the FDA's finding that there was "a reasonable assurance" of the device's safety and effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

27. However, the PMA imposed certain conditions on Femcare's distribution of the product, including certain labeling requirements and restrictions on false or misleading advertising.

28. The Medical Device Amendments of 1976, 21 U.S.C. § 360(c) *et seq*. (the "MDA"), expressly preempt certain state law requirements, stating that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

29. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court set forth a two-step analysis for determining whether a claim is expressly preempted pursuant to the statute. 552 U.S. at 321-22.

30. First, the court must ascertain whether the federal government has established requirements applicable to the medical device at issue. *Id*. at 321. The Supreme Court concluded that any Class III device that receives premarket approval, which is specific to individual devices, satisfies this first prong of the § 360k(a) test.

31. Second, the court must determine whether the state common law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to" those imposed by federal law. *Riegel*, 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)(1)).

32. Here, the express preemption provision "does not [, however,] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riege*l, 552 U.S. at 330

d. Plaintiff's Claims are Not Preempted by Federal Law Because They Do Not Impose Additional Requirements on the Defendants.

33. Personal injuries caused by a medical device were not swept away on the day the MDA was enacted in 1976.

34. The PMA process does not establish that a medical device manufacturer and/or distributor are entirely immune from liability.

35. § 360k(a) does not preempt state-law claims against a medical device manufacturer based on duties that parallel federal requirements because such claims do not impose requirements that are "different from, or in addition to" those imposed by federal law.

36. State tort law provides a right of action to a person who is injured when a device manufacturer's noncompliance with federal reporting standards results in a failure to warn of the risks of using a device and causes injury to a patient.

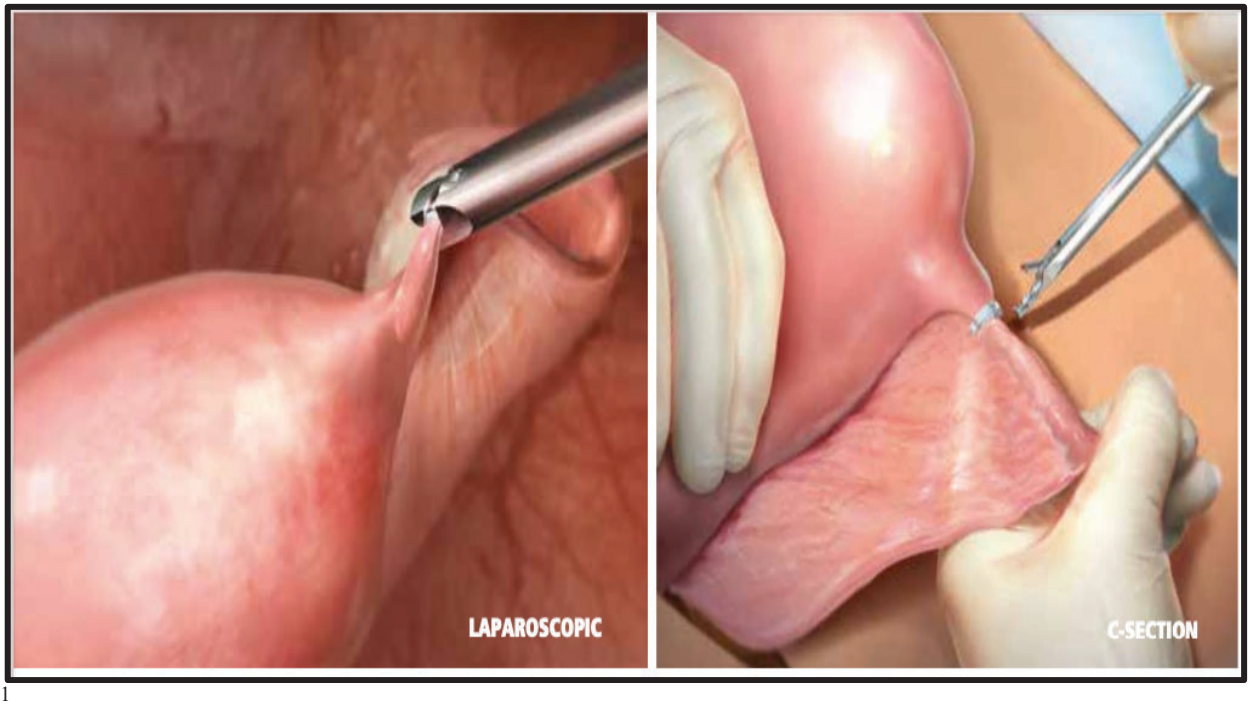
e. CooperSurgical, Femcare, Ltd., and Utah Medical Products Design and Promote Defective Filshie Clips.

37. Defendants, CooperSurgical, Femcare, Ltd., and Utah Medical Products, singularly and in combination, designed, manufactured, sold and distributed Filshie Clips and related equipment utilized in Plaintiff's tubal ligation.

38. For years, Defendants intentionally manufactured sold and distributed Filshie Clips to the public as a quick, easy, and simple form of sterilization. Defendants told women they could use Filshie Clips to effectively prevent pregnancy while the product was in place and that the product was safe. Defendants' representations were false.

39. Created by Marcus Filshie in the late 1970s, more than 12 million women worldwide have undergone tubal ligation with the Filshie Clip method.

40. The Filshie Clip works by exerting continued pressure on the fallopian tube, causing avascularization for the 3- to 5-mm area it encompasses. The silicone continues this pressure even after necrosis starts and the fallopian tube decreases in size. Fibrosis then occurs, and the clip is peritonealized. The clips are placed perpendicular to the isthmic portion of the tube, so that it completely encompasses the tube, and the lower edge of the jaw can be seen in the mesosalpinx.



[1]

[1] Medical drawing of Filshie Clips being applied in a laparoscopic and c-section procedure provided by CooperSurgical in their surgical products catalog.

41. The Filshie Clip System was manufactured and promoted prior to 1996 in Europe and elsewhere. In 1996, the Filshie Clip System received Pre-Marketing Approval (PMA) from the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA) after information was submitted regarding, among other things, the safety and efficacy of the system.

42. Subsequently, the Filshie Clip System was marketed and sold throughout the United States, including the State of Ohio.

f. CooperSurgical, Femcare, Ltd., and Utah Medical Products Failed to Inform Patients of the Risks Associated with Filshie Clips.

43. It should go without saying that it is of the utmost importance that women know all risks associated with a particular type of birth control given that a women's choice of birth control can have long-term consequences on her health.

44. Filshie Clips pose significant health risk, and the product has subjected untold thousands of women to significant injuries. These injuries stem from the simple fact that Filshie Clips have a propensity to migrate after being placed on the fallopian tubes. Migration of the clips following a normal application is estimated to occur over 25% of the time. The pathophysiology is related to the speed at which peritoneal-like tissue forms over the clip anchoring it to the fallopian tube.[2]

45. The migration of the clip often requires surgical intervention to remove the Filshie Clips from the woman's body. Defendants neither warned nor adequately informed Plaintiff nor her healthcare providers how frequently these migrations occur or the severity and permanency of

[2] G. Marcus Filshie, *Female sterilization: medico legal aspects,* Reviews in Gynaecological Practice; Vol.1 Summer 2001.

the potential injuries even though Defendants had received adverse reports and knew or should have known Filshie Clips had a significant propensity to migrate.

46. Women and their doctors depend on Defendants, the manufacturers and distributors of products like Filshie Clips, to be forthcoming about the safety and risks of Filshie Clips. This reliance on Defendants was warranted. The regulatory scheme that governs Filshie Clips is premised on a system whereby the manufacturer is responsible for reporting relevant safety information to the public.

47. The onus is on the manufacturer to come forward with any safety risks because the public and the U.S. Food and Drug Administration ("FDA") would otherwise have no insight of adverse events.

48. The Plaintiff has suffered as a result of Defendants' failure to report adverse events involving the Filshie Clip. That failure violated requirements imposed by the Food and Drug Administration (FDA).

49. During the premarket approval process, it was reported to the FDA that the Filshie Clip System had a migration incidence of .13%.

ADVERSE EFFECTS

The following adverse effects have been reported with the use of the Filshie Clip (see Table 1).

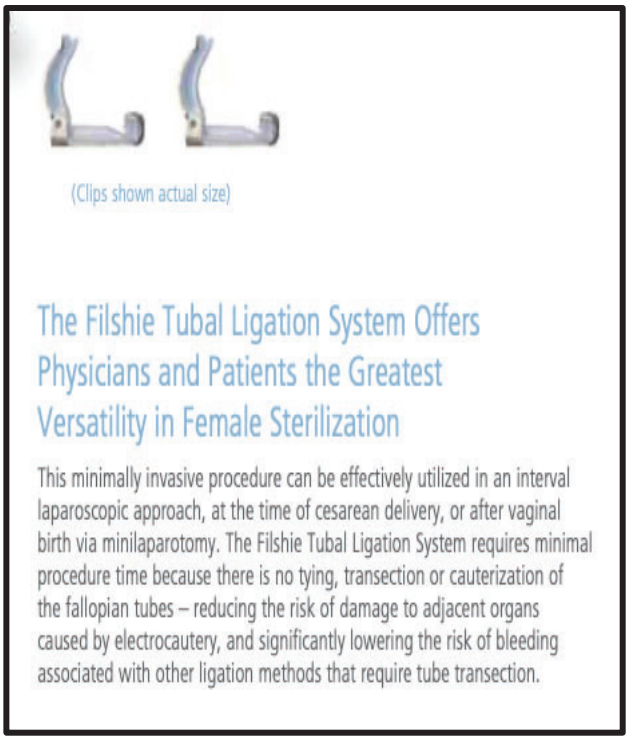
pregnancy (0.46%); ectopic pregnancy (0.016%); clip migration or expulsion (0.13%); misapplication to ovarian ligament, broad ligament, omentum, bowel, tubal serosa, cornual or broad ligament (0.05%); pain and cramping (35.7%);

50. However, the risk of clip migration was significantly higher and continued to increase from year to year since the initial PMA. Despite these increases, Defendants failed to

address the Filshie Clips safety issues, even though adverse event reports did or should have alerted them to a product defect causing the device to cause injuries.

51. Rather than inform of the risks, CooperSurgical, Femcare, Ltd., and Utah Medical Products tout the benefits of the Filshie Clip version of the bilateral tubal ligation procedure over other available procedures. As noted in the press release regarding the Femcare, Ltd. Purchase, the Filshie Clip System was claimed to be "safer than electrocautery and the newer hysteroscopic devices" without mention of the risk of migration associated with the clips.

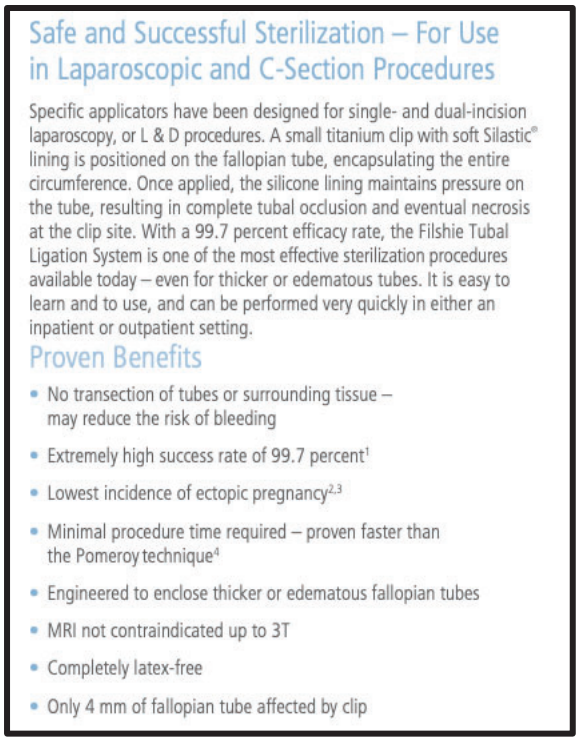
> In summary, the Filshie Clip is as effective as the newest occlusive devices and much more effective than the more traditional sterilization approaches, is as easy or easier to place as any of the traditional techniques and easier than the newer hysteroscopic devices, is safer than electrocautery and the newer hysteroscopic devices when placed by less than well-trained and skilled clinicians, and has a substantially higher probability of reversibility when compared to all of the other approaches for women who later decide they may like to get pregnant.



(Clips shown actual size)

The Filshie Tubal Ligation System Offers Physicians and Patients the Greatest Versatility in Female Sterilization

This minimally invasive procedure can be effectively utilized in an interval laparoscopic approach, at the time of cesarean delivery, or after vaginal birth via minilaparotomy. The Filshie Tubal Ligation System requires minimal procedure time because there is no tying, transection or cauterization of the fallopian tubes – reducing the risk of damage to adjacent organs caused by electrocautery, and significantly lowering the risk of bleeding associated with other ligation methods that require tube transection.



Safe and Successful Sterilization – For Use in Laparoscopic and C-Section Procedures

Specific applicators have been designed for single- and dual-incision laparoscopy, or L & D procedures. A small titanium clip with soft Silastic® lining is positioned on the fallopian tube, encapsulating the entire circumference. Once applied, the silicone lining maintains pressure on the tube, resulting in complete tubal occlusion and eventual necrosis at the clip site. With a 99.7 percent efficacy rate, the Filshie Tubal Ligation System is one of the most effective sterilization procedures available today – even for thicker or edematous tubes. It is easy to learn and to use, and can be performed very quickly in either an inpatient or outpatient setting.

Proven Benefits

- No transection of tubes or surrounding tissue – may reduce the risk of bleeding
- Extremely high success rate of 99.7 percent[1]
- Lowest incidence of ectopic pregnancy[2,3]
- Minimal procedure time required – proven faster than the Pomeroy technique[4]
- Engineered to enclose thicker or edematous fallopian tubes
- MRI not contraindicated up to 3T
- Completely latex-free
- Only 4 mm of fallopian tube affected by clip

52. Defendants had a duty to act as reasonable manufacturers and distributors of medical devices. They had a duty to continually monitor their product, including, but not limited to, its design, manufacturing, performance, safety profile, and labeling. They had a duty to continually test their product and ensure it was safe and would perform as intended. Yet Defendants breached their duties and, as a result, Plaintiff was injured.

53. The knowledge Defendants have regarding the migration issues involved with the Filshie Clip Systems not only triggers responsibility under Ohio law for product liability, they also imposed parallel duties on the Defendants pursuant to the Food, Drug, and Cosmetic Act (FDCA) to accurately report and update the FDA of the same. These duties, both under Ohio product liability law and the FDCA, are substantially similar. The Ohio product liability law does not impose a higher standard than the FDCA.

54. If Defendants had timely disclosed the propensity and severity of risks associated with use of the Filshie Clips, Plaintiff's injuries could have been avoided. Instead, Defendants did nothing, and for that, Plaintiff here seeks redress both to compensate her for her losses and to strongly deter future, similar misconduct.

55. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Filshie Clips in, among others, the following ways:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

(b) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices or procedures available for the same purpose;

(c) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

(d) Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers or the general health care community about Filshie Clip's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

(e) Failing to perform reasonable pre-and post-market testing of the Filshie Clips to determine whether or not the product was safe for its intended use;

(f) Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the Filshie Clips;

(g) Advertising, marketing and recommending the use of the Filshie Clips, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the Filshie Clips;

(h) Representing that Filshie Clips were safe for their intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

(i) Continuing manufacture and sale of Filshie Clips with the knowledge that the they were dangerous and not reasonably safe, and failing to comply with FDA manufacturing regulations;

(j) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Filshie Clips so as to avoid the risk of serious harm associated with the use of the Filshie Clips;

(k) Failing to establish an adequate quality assurance program used in the manufacturing of the Filshie Clips;

(l) Failing to establish and maintain an adequate post-marketing surveillance program for Filshie Clips;

Failing to adequately and correctly report safety information related to the Filshie Clips product resulting in inadequate warnings; and

(m) Failing to provide adequate and continuous warnings about the inherent danger of migration with Filshie Clips after they had been placed on the fallopian tubes.

Ms. Arnold's experience with the Filshie Clips

g. Plaintiff is Implanted with CooperSurgical/Femcare, Ltd. Filshie Clips.

56. In early 2003, Ms. Arnold underwent a tubal ligation procedure.

57. The tubal ligation procedure used Filshie Clips.

58. Plaintiff was provided with a Disclosure and Consent for medical and surgical procedures which included generic risks and hazards associated with the procedure. No mention was made of the risk of migration and the appurtenant damages that could be caused by the Filshie Clips. The only risks mentioned were associated with the ligation procedure itself.

59. At the time, and upon information and belief to date, the product information sheet supplied to her healthcare providers made no mention of the actual rate of migration known of the Filshie Clips.

60. In March of 2003, Plaintiff first began experiencing pain and discomfort in her lower abdominal and pelvic region. Plaintiff's pain has developed over nearly 20 years to include acute areas of the lower abdominal and pelvic region.

61. To this day, Plaintiff continues to struggle with chronic pain caused by Filshie Clip migration.

h. Ms. Arnold Discovers The Cause of Her Suffering.

62. In January of 2022, Plaintiff's doctor identified a migrated Filshie Clip in a medical scan of Plaintiff's lower abdominal region.

63. Plaintiff was subsequently informed that the Filshie Clips remained in her body and were displaced.

64. Plaintiff is in the process of scheduling a surgery to remove the clips but continues to live under the specter of having a foreign body migrating through her pelvic area.

65. The design, manufacture and warnings of the CooperSurgical, Femcare, Ltd. and Utah Medical Products devices at issue in this case exhibited several defects that violated common-

sense consumer expectations, as well as the expectations of the medical professionals involved in gynecological care.

66. The Filshie Clips, which were warranted, marketed, and purported to be permanently in place on the fallopian tubes, were defective.

67. Evidence of the Filshie Clips propensity to migrate was available to Defendants and should have been relayed to the physicians by way of warning on the product packaging or other dissemination of the information.

68. To date, Defendants have failed to adequately warn of these dangers, and certainly hadn't done so at the time Plaintiff consented to the Filshie Clip method of sterilization.

69. As a result of the design, manufacture, and marketing defects of the Filshie Clips, Plaintiff (and a large number of the women in the world who had submitted to their use) has experienced significant pain, suffering, and surgeries she otherwise would not have had she chosen one of the other methods of sterilization available to women.

V. THE DISCOVERY RULE APPLIES TO THIS MATTER

70. All of the allegations contained in the previous paragraphs are realleged herein.

71. Plaintiff plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff has been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

72. Despite diligent investigation by Plaintiff of the cause of her injuries, the nature of Plaintiff's injuries and damages and their relation to Filshie Clips and Defendants' wrongful conduct was not discovered and could not have been discovered, until a date within the applicable statute of limitations.

73. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed within the applicable statutory limitations period.

74. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts.

75. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part.

76. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their Filshie Clips.

VI. CAUSES OF ACTION

COUNT 1: ALL DEFENDANTS – STRICT PRODUCTS LIABILITY – DESIGN DEFECT UNDER THE OHIO PRODUCT LIABILITY ACT, OHIO REV CODE § 2307.75

77. All of the allegations contained in the previous paragraphs are realleged herein.

78. The Filshie Clips are inherently dangerous and defective, unfit and unsafe for their intended use and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers. These defects were not known to be unsafe by the ordinary consumer who consumes the product with the ordinary knowledge common to the community.

79. The Filshie Clips reached their intended consumer without substantial change in the condition in which they were in when they left Defendants' possession.

80. The Filshie Clips were defective in design because they failed to perform as safely as persons who ordinarily use the products would have expected at the time of use.

81. The Filshie Clips used in Plaintiff were defective in design, because Filshie Clips risk of harm exceed their claimed benefits. Namely, the Filshie Clips System as designed allows for migration from the implantation site which increases the risk of injury from the foreign body (the clips themselves) as they float freely.

82. The design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration. The incidence of migration is reported at 25%, a significant increase from the .13% currently reflected in the product information sheets. This information was available to the designer, manufacturer, and distributor at the time of the PMA. Further, the increased incidence of migration reported since 1996 was not reported to the FDA; a continued duty and requirement after obtaining the PMA. Such failure allowed for the defective design to remain the same.

83. Plaintiff and her healthcare providers used the Filshie Clips in a manner that was reasonably foreseeable to the Defendants. In fact, they were used precisely as called for in their design.

84. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the Filshie Clips' defective conditions or perceived their unreasonable dangers prior to use. To the extent the product information sheet did report the risk of migration, it was clearly understated and unlikely to inform a reasonable consumer/patient or their healthcare providers of the risk of harm.

85. As a result of the foregoing design defects, the Filshie Clips created risks to the health and safety of Plaintiff that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Filshie Clips.

86. Defendants have intentionally and recklessly designed the Filshie Clips with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

87. As a proximate result of the Defendants' design of the Filshie Clips, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

88. As a result of Defendants' conduct, Plaintiff has been damaged and continues to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

COUNT 2: ALL DEFENDANTS – PRODUCTS LIABILITY – MANUFACTURING DEFECT UNDER THE OHIO PRODUCT LIABILITY ACT, OHIO REV CODE § 2307.74

89. All of the allegations contained in the previous paragraphs are realleged herein.

90. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed medical vigilance, distributed and sold the Filshie Clips that were used on Plaintiff.

91. The Filshie Clips used in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the Filshie Clips left Defendants' control and possession.

92. Plaintiff and Plaintiff's health care providers used the device in a manner consistent with and reasonably foreseeable to Defendants.

93. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

94. The Filshie Clips were defectively and/or improperly manufactured or constructed, rendering them defective and unreasonably dangerous and hazardous to Plaintiff.

95. Defendants had a duty to prevent the defective and/or improper manufacturing defects. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

96. Defendants have intentionally and recklessly manufactured Filshie Clips with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

97. As a proximate result of the Defendants' manufacture of Filshie Clips, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

98. As a result of Defendants' conduct, Plaintiff has been damaged and continues to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendants' conduct.

COUNT 3: ALL DEFENDANTS – STRICT PRODUCT LIABILITY – FAILURE TO WARN UNDER THE OHIO PRODUCT LIABILITY ACT, OHIO REV CODE § 2307.76

99. All of the allegations contained in the previous paragraphs are realleged herein.

100. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the Filshie Clips, including the ones used on Plaintiff, in stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

101. At the time Defendants designed set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the Filshie Clips in

the stream of commerce, Defendants knew or should have known that the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

102. Specifically, Defendants knew or should have known that the Filshie Clips posed an unreasonable risk of migration from the implantation site, resulting in significant injuries.

103. Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate warnings concerning the risk the device could migrate, even if used properly. This duty parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marketing approved by the FDA.

104. The Defendants had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for migration of the Filshie Clips under the FDCA and parallel Ohio product liability laws.

105. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Filshie Clips, and the complete lack of a safe, effective procedure for preventing migration. Rather, Defendants affirmatively advertised the safety of the Filshie Clip system vis a vis the alternative methods of bilateral tubal ligation, effectively downplaying even the de minimis risk of migration or expulsion reported to the FDA for approval of the device.

106. The risks associated with the Filshie Clips are of such a nature that health care providers and users could not have recognized the potential harm. The risks are further of the kind that a reasonable patient would consider when giving consent for the use of the Filshie Clip method of tubal ligation over other safer alternative procedures for achieving the same result.

107. The Filshie Clips were defective and unreasonably dangerous at the time of their release into the stream of commerce due to the inadequate warnings, labeling and/or instructions accompanying the product, including but not limited to, the potential for migration from intended location after placement on the fallopian tubes.

108. The Filshie Clips, when used in Plaintiff, were in the same condition as when they were manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

109. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

110. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the Filshie Clips, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

111. As a result of Defendants' conduct, Plaintiff has been damaged and continues to sustain damages in an amount to be determined by a jury but in an amount exceeding $75,000.00, as a direct and proximate result of the Defendant's conduct.

VII. RESERVATION OF RIGHTS

112. Plaintiff reserves the right to prove the amount of damages at trial. Plaintiff reserves the right to amend its Petition to add or remove counts upon further discovery and as its investigation continues.

VIII. JURY DEMAND

113. Pursuant to Federal Rule of Civil Procedure 38, Plaintiff hereby requests that all

causes of action alleged herein be tried before a properly impaneled jury.

IX. PRAYER FOR RELIEF – DAMAGES

114. The conduct of the Defendants, as alleged hereinabove, was a direct, proximate and producing cause of the damages to Plaintiff and of the following general, special, and punitive damages including:

(a) All available compensatory damages for the described losses with respect to each cause of action;

(b) Past and future medical expenses, as well as the cost associated with past and future life care;

(c) Past and future lost wages and loss of earning capacity;

(d) Past and future emotional distress;

(e) Consequential damages;

(f) All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

(g) Damages to punish Defendants for proximately causing physical pain and mental anguish;

(h) Enter judgment against Defendants, jointly and severally, awarding Plaintiff damages in an amount to be determined at trial and her costs and reasonable attorney's fees including, compensatory damages in an amount sufficient to fairly and completely compensate her for all damages;

(i) Punitive damages;

(j) Attorney's fees;

(k) Prejudgment and post judgment interest, costs, and disbursements;

(l) Any and all other recoverable personal injury damages for Plaintiff; and

(m) Such and further relief at law or in equity as this Court may deem just and appropriate.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands that the Defendants be cited to appear and answer herein. Upon final judgment against the Defendants, and each of them, jointly and severally, awarding Plaintiff damages in an amount to be determined at trial and her costs and reasonable attorney's fees including, compensatory damages in an amount sufficient to fairly and completely compensate her for all damages listed herein and such and further relief at law or in equity as this Court may deem just and appropriate.

Dated: _____, 2022

Respectfully submitted,

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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

The undersigned certifies that on this _____ day of _____, 2022, a true and correct copy of the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all known counsel of record.

GRIFFIN PURNELL LLC

By: /s/ *Simon B. Purnell*
Simon B. Purnell